DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

January 21, 2015

NuVasive, Incorporated
Ms. Michelle Cheung
Regulatory Affairs Associate
7475 Lusk Boulevard
San Diego, California 92121

Re: K143065
Trade/Device Name: NuVasive® ALIF Buttress Plate System
Regulation Number: 21 CFR 888.3060
Regulation Name: Spinal intervertebral body fixation orthosis
Regulatory Class: Class II
Product Code: KWQ
Dated: October 23, 2014
Received: October 24, 2014

Dear Ms. Cheung:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Vincent J. Devlin -S

for

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*

K143065

Device Name
NuVasive® ALIF Buttress Plate System

Indications for Use *(Describe)*

The NuVasive ALIF Buttress Plate System is an anterior non-load bearing plate system that may be used in the thoracic, lumbar and sacral spine (T1-S1). The NuVasive ALIF Buttress Plate System, in conjuction with traditional rigid fixation, is intended for use in spinal fusion procedures as a means to maintain the relative position of weak bony tissue such as allografts and autografts. This device is not intended for load bearing applications.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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510(k) Summary

In accordance with Title 21 of the Code of Federal Regulations, Part 807, and in particular 21 CFR §807.92, the following summary of information is provided:

A. Submitted by:

Michelle Cheung
Regulatory Affairs Associate
NuVasive, Incorporated
7475 Lusk Blvd.
San Diego, California 92121
Telephone: (858) 909-1800

Date Prepared: January 21, 2015

B. Device Name

Trade or Proprietary Name:	NuVasive® ALIF Buttress Plate System
Common or Usual Name:	Buttress Plate
Classification Name:	Spinal Intervertebral Body Fixation Orthosis
Device Class:	Class II
Classification:	21 CFR § 888.3060
Product Code:	KWQ

C. Predicate Devices

The subject *ALIF Buttress Plate System* is substantially equivalent to the following predicate devices:

Primary Predicates

- K021039, Depuy AcroMed BowTi Anterior Buttress Staple System

Additional Predicates

- K121837, NuVasive Brigade® Anterior Plate System
- K072339, NuVasive Anterior Lumbar Plate System
- K072943, X-spine Systems Butrex™ Buttress Plating System
- K040130, SeaSpine Anterior Lumbar Buttress System
- K090415, Eminent Spine Fang Plate System

D. Device Description

The *NuVasive ALIF Buttress Plate System* is an anterior non-load bearing plate system manufactured from Ti-6Al-4V per ASTM F1472 or Ti-6Al-4V ELI per ASTM F136, Nickel-Cobalt-Chromium-Molybdenum Alloy (Carpenter MP35N™ Alloy) per ASTM F562, and Nitinol SE510 per ASTM F2063. The implants are available in a variety of

different shapes and sizes to suit the individual pathology and anatomical conditions of the patient.

E. Intended Use

The *NuVasive ALIF Buttress Plate System* is an anterior non-load bearing plate system that may be used in the thoracic, lumbar and sacral spine (T1-S1). The *NuVasive ALIF Buttress Plate System*, in conjuction with traditional rigid fixation, is intended for use in spinal fusion procedures as a means to maintain the relative position of weak bony tissue such as allografts and autografts. This device is not intended for load bearing applications.

F. Technological Characteristics

The subject *ALIF Buttress Plate System* is substantially equivalent to other predicate devices cleared by the FDA for commercial distribution in the United States. The subject device was shown to have equivalent technological characteristics to its predicate devices through comparison in areas including design, intended use, material composition, and function. This device does not contain software or electrical equipment.

G. Performance Data

Nonclinical testing was performed to demonstrate the subject *ALIF Buttress Plate System* is substantially equivalent to other predicate devices. The following testing was performed:

- Static and Dynamic Cantilever Bending Testing per ASTM F1717-13

H. Conclusions

Based on the indications for use, technological characteristics, and comparison to predicate devices, the subject *ALIF Buttress Plate System* has been shown to be substantially equivalent to legally marketed predicate devices for its intended use.